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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,813	06/13/2005	Daisuke Matsumoto	10921.329USWO	9484
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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			PANI, JOHN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,813	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	John Pani	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 June 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/13/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 2, 4, 5, 6, and 19 are objected to because of the following informalities:

In reference to Claims 1, 2, 4-6, and 19

The claims each refer to "a detector" (claim 1) "the detector" (claims 2, 4-6, and 19). Because there are a variety of detectors mentioned throughout the series of claims, it is suggested to replace "a detector" in line 7 of claim 1, and each subsequent instance of "the detector" with --a height detector--and --the height detector--, respectively, in order to increase clarity. Appropriate correction is required.

In reference to Claim 4

"The time" in line 5 lacks antecedent basis in the claims. It is suggested to replace with --a time--.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In line 6, the claim refers to a pressure detected by "the detector". It is unclear whether the claim is intended to mean that "a detector" of claim 1 detects pressure, or

whether "the detector" referred to in line of claim 3 is actually "a pressure detector" in line 2 of claim 3.

NOTE: For purposes of rejections based on prior art, it has been assumed that "the detector" in line 6 was meant to be written as "the pressure detector".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,320,607 to Ishibashi (Ishibashi).

In reference to Claim 1

Ishibashi teaches a lancing apparatus (see Fig. 6) used for sampling a body fluid out of a skin by sticking an insertion element (12) into the skin, the apparatus comprising a housing including a cylindrical portion (13, 11, and 440) brought into contact with the skin, and a negative pressure generator (see col. 3 lines 30-34) that generates a negative pressure inside the cylindrical portion to cause the skin to swell upward (see Fig. 3), wherein the apparatus further comprises a detector (12) that detects that the skin has been raised to a predetermined height inside the cylindrical portion (piercing means 12 "detects" that the skin has been raised to a predetermined

height, in that when the skin is raised to the height of **12**, it is pierced).

In reference to Claim 17

Ishibashi teaches a lancing apparatus according to claim 1 (see above), wherein the cylindrical portion of the housing includes a plurality of members (**13, 11, and 440**), and one or more of the members (**440**) are removable from another (**11**) (See Fig. 6).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 9-11, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/07599 to Takinami et al. (Takinami) in view of US Pat. No. 4,600,403 to Wagner (Wagner). However, US2003/0109808 is considered an English language equivalent by examiner and will be referred to heretofore. See MPEP s. 901.05(III) and 2131.01.

In reference to Claim 1

Takinami teaches a lancing apparatus (**1**) used for sampling a body fluid out of a skin by sticking an insertion element (**141**) into the skin, the apparatus comprising a housing (**2**) including a cylindrical portion (**5 and 13**) brought into contact with the skin, and a negative pressure generator (**8**) that generates a negative pressure inside the cylindrical portion to cause the skin to swell upward (See Fig. 17), however, Takinami

does not teach that the apparatus further comprises a detector that detects that the skin has been raised to a predetermined height inside the cylindrical portion.

Wagner teaches of a suction injector that uses vacuum in order to draw the skin up into a cylindrical channel so that a material can be injected into the skin through a cannula (see col. 7 lines 34-57). Wagner further teaches that injection could be triggered using a contact rod that determines when the skin has reached a proper height. When the skin is at a proper height the contact rod operates a sensor switch (see col. 5 lines 16-22).

It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the sampling device taught by Takinami by including a contact rod to determine when the skin has reached a proper height and thereby setting off a sensor switch as taught by Wagner, and further automating the process by sending this signal from the sensor switch to the controller taught by Takinami, as this would prevent the lancet from firing before the skin was in a proper position.

In reference to Claim 2

Takinami in view of Wagner teaches an apparatus according to claim 1 (see above), and Takinami further comprises a controller (11) that executes a control to maintain a pressure (see [0373]) inside the cylindrical portion within a specific range (see [0373]).

Takinami as modified by Wagner in claim 1 uses the height detector to determine when the skin has been raised to a predetermined height prior to lancing. Takinami maintains the pressure in the cylindrical portion from a time prior to lancing, during

lancing, and after lancing (See Fig. 20). Therefore, Takinami in view of Wagner maintains the pressure within a specific range after the detector has detected that the skin has been raised to the predetermined height, since the lancet is fired only after the height sensor is activated, and the controller maintains pressure after the lancet is fired.

In reference to Claim 3

Takinami in view of Wagner teaches an apparatus according to claim 2 (see above), and Takinami further comprises a pressure detector (**27**) that detects pressure inside the cylindrical portion (see [0372]). The controller (**11**) executes a control so as to maintain a pressure inside the cylindrical portion (**5 and 13**) within a specific range based on the pressure detected by the detector (see [0372-0381] and [0387]).

In reference to Claim 9

Takinami in view of Wagner teaches an apparatus according to claim 2 (see above), and Takinami further teaches that the controller (**11**) controls the operation of the negative pressure generator (**8**) so as to maintain a pressure inside the cylindrical portion (**5 and 13**) within the specific range (see [0373] and [0387]).

In reference to Claim 10

Takinami in view of Wagner teaches an apparatus according to claim 2 (see above), and Takinami further teaches a relief valve (**26**) located at a position (see Fig. 17) communicating with the inside of the cylindrical portion (**5 and 13**), wherein the controller (**11**) controls and opening and closing action (see [0378]) of the relief valve (**26**) so as to maintain the pressure (see [0408]) inside the cylindrical portion (**5 and 13**) within the specific range (see [0387]).

In reference to Claim 11

Takinami in view of Wagner teaches an apparatus according to claim 10 (see above), and Takinami further teaches that the controller (**11**) opens the relief valve (**26**) (see [0400]) when the measurement has been completed. Takinami further teaches that a specified pressure range is preferred (see [0170]). Takinami does not mention that the relief valve is used to increase the pressure if the pressure drops below a specified level. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the relief valve taught by Takinami to increase pressure if the pressure dropped below a predetermined level as this would allow for the use of a pump that only produced vacuum.

In reference to Claim 17

Takinami in view of Wagner teaches an apparatus according to claim 1 (see above), and Takinami further teaches that the cylindrical portion (**5 and 13**) includes an attachment base (**13**) to which is removably attached (The test paper could be removed by simply pulling it off, as it is fixed using a fixing portion **17**, see [0183]) a sampling element (test paper **18**) that samples a body fluid coming out of the skin by the insertion of the insertion element (see [0173]).

In reference to Claim 18

Takinami in view of Wagner teaches an apparatus according to claim 1 (see above), and Takinami further teaches that the cylindrical portion (**5 and 13**) of the housing (**2**) includes a plurality of members (**5 and 13**), and one (**13**) or more of the members are removable from another (**5**) (see Fig. 3).

In reference to Claim 19

Takinami in view of Wagner teaches an apparatus according to claim 1 (see above), and Takinami further teaches a controller (11) that controls an insertion depth into the skin based on a pressure inside the cylindrical portion (**5 and 13**) (The lancet only fires when the pressure is appropriate, thereby differentiating between no insertion depth and some insertion depth, see [0382]).

Takinami as modified by Wagner in claim 1 uses the height detector to determine when the skin has been raised to a predetermined height prior to lancing. Takinami maintains the pressure in the cylindrical portion from a time prior to lancing, during lancing, and after lancing (See Fig. 20). Therefore, Takinami in view of Wagner maintains the pressure within a specific range after the detector has detected that the skin has been raised to the predetermined height, since the lancet is fired only after the height sensor is activated, and the controller maintains pressure after the lancet is fired.

In reference to Claim 20

Takinami in view of Wagner teaches an apparatus according to claim 1 (see above), and further teaches that the negative pressure generator (**8**) comprises an electric pump (see [0169]).

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takinami in view of Wagner as applied to claim 2 above, and further in view of US Pat. No. 5,201,560 to Golden (Golden).

In reference to Claim 4

Takinami in view of Wagner teaches an apparatus according to claim 2, but does not mention that the specific range is defined by granting a specific tolerance to a reference pressure, or that the reference pressure is set at a lower value than the pressure inside the cylindrical portion at a time that the detector has detected that the skin has been raised to the predetermined height.

Golden teaches of a vacuum cup control apparatus used for picking up items. In the device a vacuum is applied to a cylindrical suction cup that is placed over an object (col. 2 lines 35-42). A sensor detects sufficient contact between the object and the suction cup (see col. 10 lines 49-65). This pressure is recorded and then the vacuum is controlled to be at a value lower than this original value (see col 11 lines 1-30). This process keeps the suction cup from losing a grip on the object of interest.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the apparatus taught by Takinami in view of Wagner by modifying the controller such that it recorded the pressure at the time when sufficient contact was detected, then set the pressure range to be lower than this pressure and controlled the vacuum pump such that the pressure stayed within this range, so that suction on the object would remain sufficient, as taught by Golden.

In reference to Claim 5

Takinami in view of Wagner and Golden teaches a device according to claim 4 (see above), and Golden further teaches that the specific range has an upper limit and a

lower limit which are set at a lower value than the pressure inside the cylindrical portion at the time the detector has detected sufficient contact (see col. 11 lines 16-24).

In reference to Claim 6

Takinami in view of Wagner teaches an apparatus according to claim 2 (see above), and Takinami as modified by Wagner in claim 2 is further capable of detecting a fluctuation of the swelling height of the skin (the contact sensor would switch on and off as the height fluctuated between contacting the contact and not contacting it). However, Takinami in view of Wagner does not teach that the controller controls the pressure inside the cylindrical portion so as to maintain the swelling height of the skin at a predetermined point.

Golden teaches of a vacuum cup control apparatus used for picking up items. In the device a vacuum is applied to a cylindrical suction cup that is placed over an object (col. 2 lines 35-42). A sensor detects sufficient contact between the object and the suction cup (see col. 10 lines 49-65). This pressure is recorded and then the vacuum is controlled to be at a value lower than this original value (see col 11 lines 1-30). This process keeps the suction cup from losing a grip on the object of interest.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the apparatus taught by Takinami in view of Wagner by modifying the controller such that it recorded the pressure at the time when sufficient contact was detected, then set the pressure range to be lower than this pressure and controlled the vacuum pump such that the pressure stayed within this range, so that suction on the object (the skin) would remain sufficient, as taught by Golden. Because

the reference pressure is set when sufficient contact is detected, by maintaining the pressure in the cylinder at a value lower than that reference pressure, the swelling height would be maintained at the predetermined value.

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takinami in view of Wagner and Golden as applied to claim 6 above, and further in view of US Pat. No. 6,612,111 to Hodges et al. (Hodges).

In reference to Claim 7

Takinami in view of Wagner and Golden teaches an apparatus according to claim 6 (see above), and Takinami in view of Wagner further teaches a contacting member (The contact sensor rod taught by Wagner) for contact with the skin when the skin has been raised to the predetermined height, but the contacting member does not measure the contacting pressure of skin applied to the contacting member.

Hodges teaches of a body fluid sampling device that includes a pressure sensor for measuring the contact pressure between the device and the skin, as pressure on the sampling area can assist in extracting fluid (see col. 6 lines 32-39), and the pressure sensor assures that appropriate pressure has been applied.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Takinami in view of Wagner by modifying the contact sensor rod so that it could also measure the contact pressure applied by the skin to the device, in order to assure that sufficient pressure was applied to assist in extracting fluid, as taught by Hodges.

In reference to Claim 8

Takinami in view of Wagner and Golden and further in view of Hodges teaches an apparatus according to claim 7 (see above). It would have been further obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Takinami in view of Wagner, Golden, and Hodges so that the controller maintained the pressure in the cylindrical portion such that the contacting pressure stayed within a specific range. This would automate (see MPEP § 2144.04 (III)) the modification taught by Hodges (i.e., Hodges teaches that one would manually alter the pressure applied to the skin if it was not in the target range), and would thereby assure that sufficient pressure was applied to assist in extracting fluid, as taught by Hodges.

11. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takinami in view of Wagner as applied to claim 2 above, and further in view of US Pat. No. 6,083,236 to Feingold (Feingold).

In reference to Claim 12

Takinami in view of Wagner teaches an apparatus according to claim 2 (see above), but does not teach a backup chamber into which a gas inside the cylindrical portion flows when the pressure inside the cylindrical portion becomes equal or generally equal to an upper limit of the specific range, after generation of a negative pressure inside the cylindrical portion by the negative pressure generator.

Feingold teaches of a positioning ring assembly **20** for holding onto an eyeball during surgery in which the vacuum pressure is supplied from a control unit **400** which

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includes a vacuum pump **420** connected to a vacuum reservoir **422**. A valve **426** allows the vacuum stored in the reservoir **422** to be selectively released. The vacuum pressure in the reservoir is sensed by a vacuum transducer **424** (see col 4 lines 60-68).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Takinami by including a pressure reservoir (i.e. backup chamber) between the pump and the cylindrical portion, and a valve to release the vacuum in the pressure reservoir, as taught by Feingold, so that the vacuum pump need not run constantly, as implicitly taught by Feingold. If the gas pressure in the suction cup section were greater than that in the reservoir, gas would flow into the reservoir.

In reference to Claim 13

Takinami in view of Wagner and further in view of Feingold teaches an apparatus according to claim 12 (see above), and Takinami further teaches a gas supply selector (valve **26**) controlled by the controller (**11**) to select (**11** controls opening and closing of **26**) whether to supply a gas into the cylindrical portion (When the valve is opened, air can flow in.)

In reference to Claim 14

Takinami in view of Wagner and further in view of Feingold teaches an apparatus according to claim 13 (see above), and Takinami includes a cylindrical portion pressure detector (**27**) that detects pressure inside the cylindrical portion, wherein the gas supply selector comprises a relief valve (**26**) opened or closed according to a detecting result given by the cylindrical portion pressure detector (see [0373]).

In reference to Claim 15

Takinami in view of Wagner and further in view of Feingold teaches an apparatus according to claim 12 (see above), and Feingold further teaches that the backup chamber can be decompressed by the negative pressure generator (see col. 4 lines 60-67).

In reference to Claim 16

Takinami in view of Wagner and further in view of Feingold teaches an apparatus according to claim 15 (see above), and Feingold further teaches a backup chamber pressure detector (**424**) that detects a pressure inside the backup chamber (vacuum reservoir **422**), wherein the vacuum pump **420** decompresses **422** as needed based on feedback from **424** (see col. 4 lines 60-67).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 7/18/07

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